

Kenneth Petersen, DVM, MPH
Executive Associate for Regulatory Operations

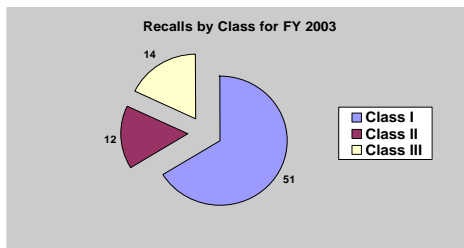
USDA:FSIS
Washington, D.C

Recall Defined

- A firm's voluntary removal of distributed meat, poultry, or egg products from commerce when there is reason to believe they are adulterated or misbranded under the FMIA, PPIA or EPIA

Recall Classes

- Class I: Reasonable probability of serious, adverse health problem or death
- Class II: Remote probability of adverse health problem
- Class III: No adverse health consequences
- Class I and Class II are therefore public health related



District Recall Officer (DRO)

- DDM where the recalling firm is located
- Coordinates field recall process
- Assigns EIAO (Enforcement Investigations and Analysis Officer)
- Interacts with recalling firm, other districts, and RMD
- Develops effectiveness check strategy

FSIS Pathogen Result Terms

- Potential Positive – screening test
- Presumptive Positive (90% will confirm)
- Confirmed Positive – product adulterated

District Office Recall Responsibilities

- 24/7 availability
- Reviews lab results routinely
- For all presumptive positives, DRO verifies product holding status and notifies

RMD – typically within 2-3 hours

- If **yes (product is held)**, no recall action
- If **no (product in commerce)**, DDM assigns EIAO. Pre-recall process begins.

Stage I- Pre Recall

Presumptive Positive

EIAO will:

- Immediately contact establishment's Recall Coordinator (RC) to discuss presumptive positive findings.
- Ensure firm receives recall worksheets. Walk-thru worksheets with company RC.
- Gathers supplier documentation in cases of *E. coli* O157:H7 per Notice 47-02 (applicable whether product is held or not)

Stage II- Recall Committee

Laboratory result confirms positive

- Recall Committee convenes for deliberations
- Multiple program area participation, 24/7
- Committee's recommendation to Assistant Administrator of Field Operations

Stage III (Post Recall)

- Company conducts a voluntary recall. RMD issues a recall notification report (RNR). CPA issues a press release. Post on website.
- EIAO verifies distribution information.
- DRO directs the EIAO to begin recall effectiveness checks.
- If product has been distributed in other Districts, DRO notifies other DDMs that assistance in conducting recall effectiveness checks is needed
- Other Districts conduct effectiveness checks and report results back to DRO
- If there is a MOU with a state (9 CFR 390.9), state authorities notified
- DRO recommends closure to RMD

Recall Effectiveness

- Verification of firm communication to consignees
- Historically – fixed percent of consignees
- New effectiveness check process based on Science and Public Health Risk
- Risk = Hazard + Exposure
- Verify effectiveness and product disposition
- Enforcement

STEPS: System Tracking

E. coli O157:H7 Positive Suppliers

- Database of plants that supplied production from an agency positive for *E. coli* O157:H7
- Districts enter supplier information. RMD maintains the database. TSC analysis.
- Generates notification to supplier plant.
- For repeat suppliers agency conducts HACCP verification procedures, CSO

- assessments, team FS assessments
- Public health surveillance tool

Key FSIS Recall Activities: Summary

- Recall management - proactive
- Accountability: District Recall Officer
- Reaction at presumptive positive stage
- Effectiveness checks – risk based
- *E. coli* O157:H7 supplier database
- CCMS